

Patent Application

for

ADJUSTABLE ABLATABLE INLAY

by

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Related Applications

**[0001]** This application is related to U.S. Application Serial No. 09/758,263, filed January 12, 2001, the entire contents of which are herein incorporated by reference.

Field of the Invention

**[0002]** The present invention relates to a method for modifying a live cornea to correct refractive error. In particular, the live cornea is modified by using a laser to separate an internal area of the live cornea into first and second opposed internal surfaces, which define a pocket therebetween. An ocular material is then introduced into the pocket, which changes the shape of the cornea. Additionally, the ocular material can be irradiated, which will cause a portion of the ocular material to expand or contract, thereby further changing the shape of the cornea.

Background of the Invention

**[0003]** A conventional method for correcting the refractive error in a cornea is keratophakia, i.e., implantation of a lens inside the cornea. Keratophakia uses an implant which is placed into the cornea approximately equidistant from the exterior

surface of the cornea and the interior surface. The procedure is usually done by first preparing a lens from corneal donor tissue or synthetic material using a cryo-lathe. The lens is implanted by removing a portion of the cornea with a device called a microkeratome, and the tissue is sutured back into place over the lens. However, there can be problems when microkeratomies are used for cutting the cornea. First, irregular keratectomies or perforations of the eye can result. Second, the recovery of vision can be rather prolonged.

**[0004]** Another surgical technique exists that uses a femtosecond laser to separate layers inside the stromal, at least two-thirds of the distance from the top surface of the cornea to the inside of the eye. An incision is made to access this area and a solid inlay is inserted to help correct myopia in the eye. By separating the layers in the bottom two-thirds of the stromal, it is difficult to access the separated area to insert the inlay and virtually impossible to change or modify the inlay without another extensive surgical procedure. This procedure requires making an incision which is parallel to the visual axis and is limited in the lateral direction by a maximum size of 0.3mm to encase a relatively rigid inlay that forces the tissue in the lateral direction.

**[0005]** Additional surgical techniques exist that use ultraviolet light and short wavelength lasers to modify the shape of the cornea. For example, excimer lasers, such as those described in U.S. Patent No. 4,840,175 to Peyman, which emit pulsed ultraviolet radiation, can be used to decompose or photoablate tissue in the live cornea so as to reshape the cornea.

**[0006]** Specifically, the Peyman patent discloses the laser surgical technique known as laser in situ keratomycosis (LASIK). In this technique, a portion of the front of the live cornea can be cut away in the form of a flap having a thickness of about 160 microns. This cut portion is removed from the live cornea to expose an inner surface of the cornea. A laser beam is then directed onto the exposed inner surface to ablate a desired amount of the inner surface up to 150-180 microns deep. The cut portion is reattached over the ablated portion of the cornea and assumes a shape conforming to that of the ablated portion. Additionally, in the Lasik procedure, a femtosecond laser can be used to cut and separate the flap.

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**[0013]** Still another object of the present invention is to provide a method for modifying the cornea of an eye that allows for corrective measures that avoid or eliminate outbulging or instability in the cornea.

**[0014]** Yet another object of the present invention is to provide a method for modifying the cornea of an eye that avoids or eliminates most of the risks of damage due to use of knives or other mechanical instruments.

**[0015]** The foregoing objects are basically attained by a method of modifying the curvature of a cornea of an eye, the cornea having a surface and a main optical axis. The steps include aiming a laser at the cornea, firing the laser at the cornea and separating an internal portion of the cornea, forming a first internal surface and a second internal surface. The first internal surface faces in a posterior direction of the cornea and the second internal surface faces in an anterior direction of the cornea, forming an internal pocket therebetween. An opening is formed from the surface of the cornea to the internal pocket, and an ocular material is introduced through the opening and into the internal pocket of the cornea.

**[0016]** Other objects, advantages, and salient features of the present invention will become apparent to those skilled in the art from the following detailed description, which, taken in conjunction with the annexed drawings, discloses preferred embodiments of the invention.

#### Brief Description of the Drawings

**[0017]** Referring to the drawings which form a part of this disclosure:

**[0018]** Fig. 1 illustrates a method of forming a pocket in the cornea of an eye, by irradiating the cornea with an ultrashort pulse laser, according to the preferred embodiment of the present invention;

**[0019]** Fig. 2 is an elevational front view of the eye and the pocket of Fig. 1;

**[0020]** Fig. 3 is an elevational front view of a second embodiment of the invention wherein two pockets are formed by an ultrashort pulse laser;

**[0021]** Fig. 4 is an elevational front view of a third embodiment of the present invention wherein four pockets are formed by an ultrashort pulse laser;

**[0022]** Fig. 5 is an elevational front view of a fourth embodiment of the present invention wherein no central portion is left attached in a pocket formed by the ultrashort pulse laser;

**[0023]** Fig. 6 is an elevational front view of a fifth embodiment of the present invention wherein a needle is used to inject ocular material into a pocket formed by an ultrashort pulse laser.

**[0024]** Fig. 7 is a cross-sectional side view of the eye of Fig. 6 with a contact lens placed on the external surface of the cornea to shape the ocular material.

**[0025]** Fig. 8 is a cross-sectional side view of a eye having a ring-shaped pocket formed in between layers of the cornea with a contact lens placed on the external surface of the cornea to shape the ocular material.

**[0026]** Fig. 9 is a front elevational view of a split ring ocular implant for use in the procedure shown in Figs. 1-4 and 19-24;

**[0027]** Fig. 10 is a front elevational view of a two part ocular implant for use in the procedure shown in Figs. 1-4 and 19-24;

**[0028]** Fig. 11 is a front elevational view of a three part ocular implant for use in the procedure shown in Figs. 1-4 and 19-24;

**[0029]** Fig. 12 is a side elevational view in cross-section of the ocular implant of Fig. 9, taken along lines 12-12;

**[0030]** Fig. 13 is a side elevational view in cross-section of the ocular implant of Fig. 10, taken along lines 13-13;

**[0031]** Fig. 14 is a side elevational view in cross-section of an arcuate ocular implant for use in the procedure shown in Figs. 1-4 and 19-24;

**[0032]** Fig. 15 is a side elevational view in cross-section of multiple ocular implants stacked on top of one another for use in the procedure shown in Figs. 1-4 and 19-24;

**[0033]** Fig. 16 is a side elevational view in cross-section of an ocular implant having a non-uniform thickness for use in the procedure shown in Figs. 1-4 and 19-24;

**[0034]** Fig. 17 is a front elevational view in cross-section of an ocular implant having four separate portions for use in the procedure shown in Figs. 1-4 and 19-24;

**[0035]** Fig. 18 is a front elevational view in cross-section of an ocular implant having two portions of different thickness for use in the procedure shown in Figs. 1-4 and 19-24;

**[0036]** Fig. 19 is a side elevational view in cross section similar to that shown in Fig. 1 with the incision in the pocket open;

**[0037]** Fig. 20 is a side elevational view in cross section similar to that shown in Fig. 19, except that an annular or circular ocular implant has been introduced through the incision and between the internal surfaces; and

**[0038]** Fig. 21 is a side elevational view in cross section of a probe irradiating a portion of the ocular material to reduce the volume of the portion.

**[0039]** Fig. 22 is a side elevational view in cross section of a probe irradiating a portion of the ocular material to increase the volume of the portion.

**[0040]** Fig. 23 is a side elevational view in cross section similar to that shown in Fig. 19, except that a portion of the external surface of the cornea has been ablated by a laser.

**[0041]** Fig. 24 is a side elevational view in cross section of the cornea with a flap formed thereon and a laser ablating a portion of the ocular material.

#### Detailed Description of the Preferred Embodiment

**[0042]** As initially shown in Figs. 1, 2 and 19-24, the refractive properties of eye 10 can be altered by using laser 12 to separate an inner portion of the cornea into first internal corneal surface 14 and second internal corneal surface 16, creating internal corneal pocket 18 in the cornea 20 and then placing ocular material or an implant 22 in the pocket 18. Additionally, the cornea can be shaped by using a second laser 24 to ablate a portion 26 of the surface 28 of the cornea 16, or an external lens 29 to mold the ocular material.

**[0043]** To begin, the refractive error in the eye is measured using wavefront technology, as is known to one of ordinary skill in the art. For a more complete

description of wavefront technology see U.S. Patent No. 6,086,204 to Magnate, the entire contents of which is incorporated herein by reference. The refractive error measurements are transmitted to a computerized lathe (not shown) or other lens-shaping machine, where the shape of ocular material is determined using the information from the wavefront device. Alternatively, the ocular material 22 can be manufactured or shaped prior to the use of the wavefront technology and can be stored in a sterilized manner until that specific shape or size is needed.

**[0044]** Ocular material or inlay 22 has a first surface 21 and a second surface 23 and is porous to allow oxygen and nutrients to pass therethrough. Materials that are suitable for these purposes are preferably any polymer or hydrogel having about 50% water content; however, the water content can be any percentage desired. The ocular material may be formed from synthetic or organic material or a combination thereof. For example, the ocular material can be collagen combined with or without cells; a mixture of synthetic material and corneal stromal cells; silicone or silicone mixed with collagen; mucopolysaccharide; chondroitin sulfate; elastins; methylmetacrylate; hydrogel; any transparent material, such as polyprolidine, polyvinylpyrrolidone, polyethylenoxide, etc.; or any deformable and/or porous polymer, which can change its shape with radiation after implantation. The collagen can be a semiliquid, a gel, human or other animal, or it can be derivatized.

**[0045]** Generally, ocular material 22 is preferably about 0.5 mm to 5mm wide. The thickness is preferably about 5-2000 microns, and more preferably less than 200 microns. The inside edge can be thinner or thicker than the outside edge; for example, the inside edge can have a thickness of about 1-100 microns, while the outside edge has a thickness of about 20-3000 microns. However, the ocular material can have any thickness or configuration that would allow it to elevate or move any portion of surface 14 relative to surface 16. The thickness and position of ocular material 22 generally defines the degree of correction.

**[0046]** Preferably, ocular material 22 is a liquid or a gel that can be injected through the surface of the cornea using an injection device 25, such as a needle, without making a large incision or opening in the surface of the lens, as seen in Fig. 6.

By injecting a gel into a pocket in this manner, the gel is confined to the corneal pocket 18 and will settle or move in the pocket in a predictable configuration or distribution. In other words, the gel will not flow through the layers of the cornea, but will rather stay inside the structure or confines of the pocket. The gel can be inserted into a pocket that encompasses the entire front of the cornea, or extend past the cornea and Bowman layer to the sclera. By extending the pocket past the Bowman layer, the portion of the cornea above the pocket would become loose. The injection of the gel would allow lifting of the Bowman layer, lifting up the entire front surface of the cornea, allowing the eye to be reshaped as desired. However, the gel can be injected or positioned into any size pocket desired and the pocket does not have to encompass the entire front of the cornea. Additionally, as described below, the ocular material does not necessarily need to be a gel in this process and may be a lens or any other desired material.

**[0047]** Furthermore, the ocular material 22 can include a silicone polymer which includes loose monomers that are responsive to light (both visible and invisible) within a certain wavelength range, such as the short ultraviolet wavelength range or the blue light wavelength range. In response to the light, the monomers become aggravated, and cross-linking occurs which increases the volume of the area of ocular material 22 or a portion of the ocular material, without substantially ablating the ocular material 22, as well as fixing or hardening the ocular material.

**[0048]** The ocular material 22 can also include a polymer comprising a polycarbonate or acrylic material containing a dye or dyes manufactured, for example, by Centex Company. The dye or dyes absorb light within a certain wavelength range, such as the infrared wavelength range, which causes slight melting or reduction of the material or a portion of the ocular material, as well as solidification. This melting or reduction results in a decrease or flattening of the irradiated area of the ocular material 22, and thus reduces the volume of that area for purposes discussed in more detail below, without substantially ablating the ocular material 22.



**[0049]** See also U.S. Application Serial No. 09/532,516, filed March 21, 2000 which is herein incorporated by reference, for a further discussion of swelling or shrinking of ocular material.

**[0050]** Ocular material 22 can also be a lens. When a lens, it can be any shape or sized desired. As seen in Figs. 6-15, the lens is preferably substantially ring-shaped; but can be a circular or semicircular inlay. For example, unitary lenses 22a-c have a split 30 or have multiple portions that couple or fit together (Figs. 9 -11), lens 22b is flat (Fig. 13), lens 22d is arcuate (Fig. 14), and lens 22a has tapered edges (Fig. 12). Additionally, ocular material 22 may have any combination of these properties. When the lens has multiple portions, as seen in lenses 22f and 22g, the portions can couple together, simply abut one another, they can lay near each other, not necessarily touching each other or the lens portions can be separated from each other (Figs. 17 and 18). Lens 22b can have multiple layers on top of each other (Fig. 15), or lens 22c and 22g can have two sides with different thickness (Fig. 16 and 18), which would help to correct astigmatism. Additionally, the lens preferably allows light in the visible spectrum to pass therethrough and can have different or similar refractive properties to the refractive properties of the cornea, it can have pigmentation added thereto to change the color of the lens or it can be photochromatic. Furthermore, it is not necessary for the lens to have a hole or aperture therethrough. The lens can have a substantially planar surface or an arcuate surface with no holes or apertures therein, as seen specifically in Fig. 5.

**[0051]** As seen specifically in Figs. 1-5, a laser 12 is aimed at an internal portion of the cornea, adjacent the external surface of the cornea of the eye and fired. Preferably, the laser is focused to create the pocket 18 in the first one-third of the cornea, and not in the back of the cornea. In other words, the pocket is preferably formed adjacent surface 28 or closer to surface 28 than to the interior or anterior chamber 11 of eye 10. By forming the pocket in the first one-third of the cornea, the pocket or pockets may extend beyond the Bowmans layer and the cornea, to create a large pocket, which would allow raising of the entire front portion of the cornea, as described above. The laser preferably separates an internal area of the cornea offset

from the main optical or visual axis 32 into first 14 and second 16 substantially ring-shaped internal surfaces to form the circular or ring-shaped corneal pocket 18. First internal corneal surface 14 faces in a posterior direction of cornea 20 and the second internal corneal surface 16 faces in an anterior direction of the cornea 20. The distance from first internal corneal surface 14 to the exterior corneal surface 28 is preferably a uniform thickness of about 10-250 microns, and more preferably about 80-100 microns, but can be any suitable thickness and does not necessarily need to be substantially uniform. A portion 34 of first and second surfaces 14 and 16 preferably remains attached to each other by an area located at the main optical axis 32. However, the laser can form a pocket 18 of any suitable configuration, such as a pocket that is not attached at the main optical axis (Fig. 5), two substantially similar pockets 18 and 18' (Fig. 3) or four pockets 18, 18', 18'' and 18''' (Fig. 4). When multiple pockets are formed, preferably the pockets are separated by a portion 36, which is an area where first and second surfaces 14 and 16 remain attached. However, the pocket or pockets may be any number, shape or size desired and they do not need to be circular or ring-shaped.

**[0052]** Laser 12 preferably is an ultrashort pulse laser, such as a femto, pico, or attosecond laser; but may be any light emitting device suitable for creating a pocket in the cornea as described above. The ultrashort pulse laser is positioned in front of the eye and is focused at the desired depth in the cornea and in the desired pocket configuration. Ultrashort pulse lasers are desired since they are high precision lasers that require less energy than conventional lasers to cut tissue and do not create "shock waves" that can damage surrounding structures. Cuts made by ultrashort pulse lasers can have very high surface quality with accuracy better than 10 microns, resulting in more precise cuts than those made with mechanical devices or other lasers. This type of accuracy results in less risks and complications than the procedures using other lasers or mechanical devices.

**[0053]** As seen in Figs. 2-5, an incision or opening 38 is made in the surface 28 of the cornea to access pocket 18 or pockets 18', 18'' and 18'''. Preferably, the incision 38 is made at the periphery of the pocket; however, it may be made anywhere desired

that would allow access to the pocket 18. Additionally, multiple incisions can be made that would allow access to different portions of pocket 18 or different pockets 18', 18'' and 18'''. A carved instrument (not shown) can be inserted through the incision, which would dissect the pocket, if needed. A carved instrument is generally used to extend the pocket 18 past the cornea or Bowmans layer to the sclera as described above. However, a large incision may not be necessary, as in the case where a gel is inserted using a needle, as described above.

**[0054]** As seen in Figs. 19 and 20, the ocular material 22 is then inserted through the incision 28 or any other opening by opening the incision using any device known in the art, such as spatula or microforceps or any other device. Preferably, when a lens is used, it has at least two separate portions 40 and 42 (Fig. 10) or has a split 30 (Fig. 9) that allow the ocular material 22 to be positioned or introduced around or at least partially encircling the main optical axis 32 or portion 34 and in between the first and second internal surfaces 14 and 16 that define the pocket 18. However, as stated above the first and second surfaces 14 and 16 do not necessarily have to be attached at the main optical axis and in such a case, ocular material 22 is merely placed in pocket 18.

**[0055]** As seen in Figs. 7 and 8, when ocular material is injected or placed into pocket 18, an external contact lens 29 can be placed on the external surface of the cornea, which would allow the gel to be shaped or redistributed and, thus, the cornea to be reshaped in any manner desired. The proper size and shape of the contact lens 29 is determined by the information received from the wavefront technology. Lens 29 is preferably a temporary lens that would allow light of the visible spectrum to pass therethrough. The contact lens back surface 31 forces the gel to distribute evenly until the topographically desired configuration is achieved. Additionally, the opening 38 may allow a small amount of gel to escape, if needed, to adjust the shape and size of the ocular material 22. Wave front technology can then be used to determine if the desired correction has been achieved, and if it has not the gel can be removed via an incision and the process repeated at a later time.

**[0056]** Once the ocular material is in place, the patient's eye can be monitored or measured and a laser, probe 31 or other heating device can be used to reduce the overall thickness of the ocular material 22, if necessary. For instance, the ocular material 22 can initially be about 500 microns thick for ease of handling. Then, once the material 22 is positioned in the pocket 18 of the cornea, in the manner described above, the probe 40 (i.e., infrared light) can be directed to material 22 so as to reduce the overall thickness of material 22, as desired. Hence, a 500 micron thick portion of the material can be reduced, for example, to about 100 microns or any suitable thickness by the heating device. It is noted that when the pulsed laser light is focused properly to a location within ocular material 22, it can disrupt and thus shrink or melt ocular material 22 without the need of an absorbent dye. An example of such a laser is an ultrashort pulse laser, which emits nano-second pulses, pico-second pulses or femto-second pulses of laser light. Furthermore, laser light having a wavelength that is absorbed by water, or other types of energy such as microwave radiation, radio frequency radiation, or thermal energy, can be used to cause shrinkage in the lens.

**[0057]** As shown in Fig. 21, an area of the material is irradiated with energy  $L_1$ , such as infrared light, laser light, microwave energy, radio frequency energy, or heat applied by a probe or laser 31, to cause the area of the lens to shrink or, in other words, reduce in volume. This shrinkage occurs without damage to the ocular material or other portion of the cornea 20. Accordingly, the shrinkage causes a change in the shape of the ocular material area, and thus changes the refractive power of the cornea 20 to further correct for the remaining vision disorder that was not fully corrected by the ocular material 22. The ocular material can be irradiated directly through the cornea or through lens 29.

**[0058]** Alternatively, the patient's vision can be monitored as the cornea 20 heals to determine if the size and shape of the ocular material 22 should be increased. The size or shape of the ocular material can be changed, and therefore the curvature of the cornea 20 can be changed without surgically opening the pocket 18. That is, as discussed above, the ocular material 22 can include certain monomers which, when irradiated with light within a certain wavelength range (e.g., blue or ultraviolet light),

become agitated and cross-link, which causes the ocular material 22 to increase in size at the area of the irradiation.

**[0059]** As shown in Fig. 22, an area of ocular material 22 is irradiated by probe 33 or laser light  $L_2$ , which passes through the layer 21. The laser light  $L_2$  has a wavelength, such as long ultraviolet wavelength or light within the blue light spectrum, to aggravate the monomers, which causes a cross-linking effect that increases the volume of the ocular material 22 in the area being irradiated. Hence, as the thickness of the ocular material 22 increases, this increase thickness changes the curvature of the cornea as shown, thus changing the refractive power of the cornea to a degree necessary to correct the remainder of the vision disorder that was not corrected by the insertion of the ocular material 22. The ocular material can be irradiated directly through the cornea or through lens 29.

**[0060]** Furthermore, a chemical can be used to polymerize or solidify the ocular material, when the ocular material is a collagen solution. Preferably, the chemical is applied to the external surface of the cornea and passes through the cornea and into the pocket 18, where it comes into contact with ocular material 22 and polymerizes the material. Preferably, the chemical used to polymerize the collagen solution is preferably about, 0.1 molar to 0.5 molar and more preferably about 0.2 molar to 0.4 molar of sodium persulphate diluted in a 0.02 molar phosphate buffer having a pH of about 8.0. However, the polymerizing chemical and the ocular material may be any suitable chemical and material known to one skilled in the art.

**[0061]** Furthermore, if necessary, the collagen solution can be depolymerized or returned to a gel or liquid state by applying glugalic anhydride in the same manner as described above for sodium persulphate. However, the depolymerization chemical can be any suitable chemical known in the art. Once the ocular material is depolymerized, the procedure can be repeated as often as desired. In other words, the refractive properties of the eye can be remeasured and reset and the material can be repolymerized as many times as desired until the correct refractive measurement is achieved.

**[0062]** To clean or wash the above chemicals from the eye, a disodium phosphate of about 0.02 molar and pH of 8.5 can be applied to the surface of the cornea.

**[0063]** Once the ocular material is in place and/or cross-linked or solidified as described above, the refractive properties of the eye can be remeasured using wavefront technology, and it can be determined if any refractive error remains in the eye. Generally, the refractive error is less than  $\pm 2.0$  diopters sphere or astigmatism.

**[0064]** To reduce or eliminate this small refractive error, a second laser 44, preferably an excimer laser, can then be aimed and fired at the external surface of the cornea 24, ablating a portion 26 of the cornea, as seen in Fig. 23. Preferably, about 1-100 micron thickness is ablated, but any thickness that achieves the desired result can be ablated from the exterior surface of the cornea. The excimer laser can be applied either through the corneal epithelium or the epithelium can be reopened initially using diluted alcohol (less than 20% alcohol) or a brush. The second laser preferably ablates portion 26 of surface 22 that overlies the portion 34 attaches, but may ablate any portion desired.

**[0065]** When correcting the remaining portion with the excimer laser, it is possible to simultaneously use wavefront technology or Adaptec optic technology to create a near perfect correction in the eye and to remove all corneal irregularities. By using this technique to correct vision, it is possible to achieve 20/10 vision in the patient's eye or better.

**[0066]** The patient can undergo the second laser ablation either immediately after the insertion of the ocular implant or after a substantial time difference, such as days or weeks later, and any step or portion of the above procedure may be repeated to decrease the refractive error in the eye.

**[0067]** Additionally, as seen in Fig. 24 once the ocular material is in place, if necessary, a flap 42 can be formed in the surface of the cornea of the eye, which would expose the ocular material 22 when removed or folded away. Once the flap is removed or folded away, the ocular material can be irradiated and a portion 44 or the material 22 ablated by an excimer laser 46 and wavefront technology, as described

above. Preferably, this technique is used on the pocket having no portion attached in the center, but may be used with any type of pocket, including the ring-shaped pocket.

**[0068]** Furthermore, at the end of the procedure or before the ablation of the surface of the cornea, topical agents, such as an anti-inflammatory, antibiotics and/or an antiproliferative agent, such as mitomycin or thiotepa, at very low concentrations can be used over the ablated area to prevent subsequent haze formation. The mitomycin concentration is preferably about 0.005-0.05% and more preferably about 0.02%. A short-term bandage contact lens may also be used to protect the cornea.

**[0069]** While preferred embodiments have been chosen to illustrate the invention, it will be understood by those skilled in the art that various changes and modifications can be made therein without departing from the scope of the invention as defined in the appended claims.